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means for suspending the biomaterial, the suspending means being in dehydrated form and being directly implantable into a body.

73. (New) The composition of claim 72, wherein the suspending means comprises a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition and being implantable into a body without a grinding or resuspending operation.

REMARKS

This Reply is in response to the Office Action mailed on June 11, 2002. Claims 1-70 were originally filed in the present application, and all claims currently remain pending. Applicants also request consideration of new claims 71-73. Applicants appreciate the indication of allowability of claims 1-41, 57-64, 66 and 70, over the prior art.

First, the Examiner has asserted that claims 40-56, 65 and 69 are not entitled to priority going back to any of the claimed priority applications. In particular, the Examiner has asserted that the dehydrated composition was not described or suggested in any of the priority applications. Notwithstanding the Examiner's assertions, Applicants respectfully submit that all of these claims are indeed entitled to priority to Provisional Patent Application No. 60/148,590, filed August 13, 1999.

First, Applicants should note that claim 40 has been amended to correct an improper dependency and is now dependent upon claim 21, which the Examiner has already indicated has ample support in at least one priority application. Regarding claim 41, this claim includes several of the same limitations as independent claims 1 and 21, neither of which have had any priority issues raised by the Examiner.

Regarding claims 42-56, 65 and 67-69, all of the claims at issue are directed to a substantially dehydrated biocompatible composition. In particular, the Examiner is directed to page 35 of the originally-filed provisional application No. 60/148,590, referenced above (a copy of which is attached for the Examiner's reference). Page 35 of the provisional application

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specifically describes an embodiment of the invention where the tissue augmentation material is substantially dehydrated to result in a composition corresponding to the claims at issue. Furthermore, claims 42-56 were copied *verbatim* from claims 42-56 of the provisional application. Applicants therefore submit that these multiple references to the dehydrated composition constitute more than ample support for a claim of priority to Provisional Application No. 60/148,590. If the Examiner has any questions regarding this matter, she is strongly encouraged to contact the attorneys for Applicants.

The Examiner also rejected claims 42-56, 65 and 67-69 under 35 U.S.C. § 112, first paragraph. The Examiner has asserted that neither the specification nor the priority applications provide a description of a process to form a dehydrated composition of claims 42-56, 65 and 67-69. Once again, the Examiner is directed to both page 35 of the specification and claims 42-56 of the provisional application. All of this text was substantially copied into the current nonprovisional application. The written description, page 35, lines 11-30, clearly and thoroughly describes dehydration by drying in air, and the originally-filed claims further describe the method for dehydrating. Furthermore, the Examiner is reminded that claims included in the original application satisfy the written description. See, e.g., In re Koller, 613 F.2d 819, 823-24 (CCPA 1980). ("Original claims constitute their own description"). In addition, the claims are considered part of the written description for purposes of the requirements of Section 112. See In re Gardner, 480 F.2d 879, 880 (CCPA 1973) ('Under these circumstances, we consider the original claim in itself adequate "written description" of the claimed invention. It was equally a "written description" ... whether located among the original claims or in the descriptive part of the specification.'). See also Hyatt v. Boone, 146 F.3d 1348, 1352, 47 U.S.P.Q.2d 1128, 1130 (Fed. Cir. 1998), cert. denied, 525 U.S. 1141 (1999), ("The claims as filed are part of the specification, and may provide or contribute to compliance with Section 112"). In this case, claims 42-56 not only were included in the originally-filed nonprovisional application, they were also included in the originally-filed *provisional* application, thereby providing more than ample

support under 35 U.S.C. § 112. For all of these reasons, Applicants respectfully submit that there is sufficient written description for the claims at issue.

Additionally, Applicants have further amended claim 56 to describe the carrier as being "resorbable" instead of "resorable." The term "resorable" was originally a typographical error and was not intended to be used in the original claim. Applicants clearly do not intend to limit the scope of the claim in terms of the Doctrine of Equivalents with this amendment.

Applicants also note that claim 42 and newly independent claims 67 and 68 have been rephrased to remove potential antecedent basis issues and to clarify the claim language. In particular, the term "suspending medium for the biomaterial" has been amended to "medium for suspending a biomaterial." These amendments are being made for clarification purposes only and are not intended to narrow or alter the scope of the claims.

The Examiner has also asserted that claims 42-56, 65, and 69 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,324,775, issued to Rhee, et al. In particular, the Examiner has asserted that the Rhee, et al. reference teaches the feature of dehydrating the disclosed complex conjugates to form a solid, which can be used in tissue augmentation after the solid is converted into particles or shaped into solid objects.

In order to clarify the nature of the present invention, Applicants have amended claim 42 to describe the dehydrated composition as being directly implanted to a desired tissue site. Despite the Examiner's assertions, the Rhee, et al. reference does not disclose, teach or even suggest a dehydrated composition that can function to be shaped into solid objects for direct implantation into a patient for tissue augmentation. Instead, the Rhee, et al. reference teaches away from being able to function as a means for direct implantation into the patient by stating that any formed dehydrated, solid object is to be ground into particles, resuspended, and then injected for soft tissue augmentation by way of transdermal injection. This is particularly described at column 2, lines 27-35, and repeated at column 3, lines 25-32, and in the abstract of the invention.

The present invention, on the other hand, is directed to the manufacture of a substantially dehydrated composition which can function to be directly implanted into the tissue augmentation site, that is without grinding or resuspension. In particular, the present invention and the claims at issue are concerned with the manufacture of a material which can be formed into various shapes to prepare a preform for implantation. Importantly, this implantation occurs without any grinding or suspending operation. This concept is described in detail at page 35 of the present application. Such a direct implantation is not taught, disclosed or even suggested by the Rhee, et al. reference. For this reason, Applicants have amended claim 42 to describe the dehydrated composition as a composition for direct implantation into a desired tissue site. In other words, although the composition could be shaped after dehydration, no grinding or suspending is necessary.

Additionally, the present invention is distinguishable from the Rhee, et al. reference in a number of other respects. In particular, Applicants note that the present invention relates to polysaccharide gels rather than biologically inert polymers covalently bound with hydrophilic polymers, as is described in the Rhee, et al. reference. Additionally, the conjugate in the Rhee, et al. reference provides the structure into which cells engraft, while in the present invention it is the biocompatible particles which perform this function. For these reasons, Applicants submit that the claims at issue are allowable over the prior art.

Applicants have also added new claims 71-73. These claims are also directed to a substantially dehydrated composition that is directly implantable into a body. Applicants submit that these claims are also allowable over the prior art for the reasons described above.

Lastly, the Examiner objected to claims 68 and 67, as being dependent upon rejected claim 42. In response to this objection, Applicants have amended these claims by placing them in independent form. Applicants therefore submit that these claims are now in condition for allowance. Additionally, Applicants have further amended these claims to more clearly identify the fact that the described viscosity ranges are for the polysaccharide gel before

dehydration. Although this feature would have been apparent to one skilled in the art in light of the specification as a whole, Applicants have included this term to more clearly describe the content of the claims. Applicants do not intend to narrow the scope of the claims with these amendments.

Applicants therefore submit that all outstanding rejections to the pending claims and specifications have been overcome by the foregoing amendments and remarks, and that each of pending claims 1-73 are now in condition for allowance. Reconsideration and favorable action are hereby respectfully requested, and Applicant respectfully requests an early notice of allowance on these claims. A fee of $342.00 for three new claims (including three new independent claims) is believed to be due with this reply. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 06-1450, of Foley & Lardner. A duplicate copy of this response is attached for this purpose.

Respectfully submitted,

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APPENDIX – AMENDED AND NEW CLAIMS

40. (Once Amended) The composition according to Claim 21 [40], wherein the desired tissue site is an osseous site in a state of osteoporosis.

42. (Once Amended) A substantially dehydrated biocompatible composition, comprising a biocompatible, resorbable, [suspending] medium for suspending a [the] biomaterial, the suspending medium comprising a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition, the dehydrated composition being directly implantable into a living body.

56. (Once Amended) A method of preparing and implanting [making] a substantially dehydrated biocompatible composition [for implantation into a desired tissue site], comprising the [step] steps of drying a biocompatible composition comprising a biomaterial for augmenting a desired tissue site and a biocompatible, [resorable] resorbable, lubricious carrier for the biomaterial, the carrier comprising a polysaccharide gel having a viscosity of from about 20,000 to about 350,000 centipoise, and implanting the dehydrated composition into a desired tissue site.

67. (Once Amended) A substantially dehydrated biocompatible composition, comprising a biocompatible, resorbable, medium for suspending a biomaterial, the suspending medium comprising a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition [The composition according to claim 42],

wherein the polysaccharide gel has a viscosity before dehydration of from about 150,000 centipoise to about 250,000 centipoise.

68. (Once Amended) A substantially dehydrated biocompatible composition, comprising a biocompatible, resorbable, medium for suspending a biomaterial, the suspending medium comprising a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition [The composition according to claim 67],

wherein the polysaccharide gel has a viscosity before dehydration of from about 200,000 centipoise to about 250,000 centipoise.

71. (New) The composition of claim 42, wherein the dehydrated composition is directly implantable into a body without a grinding or resuspending operation.

72. (New) A substantially dehydrated biocompatible composition, comprising:

a biomaterial; and

means for suspending the biomaterial, the suspending means being in dehydrated form and being directly implantable into a body.

73. (New) The composition of claim 72, wherein the suspending means comprises a dehydrated polysaccharide gel for maintaining the biomaterial suspended in the implant composition and being implantable into a body without a grinding or resuspending operation.